PATENT COOPERATION TREATY

REC'D 22 FEB 2006
WIPO PCT

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference B-14928 PCT	**FOR FURTHER ACTION** See Form PCT/IPEA/416	
International application No. PCT/IB2005/000564	International filing date *(day/month/year)* 03.03.2005	Priority date *(day/month/year)* 05.03.2004
International Patent Classification (IPC) or national classification and IPC A61B18/14		
Applicant MEDELEC-MINIMECA S.A. ET AL.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
04.10.2005	17.02.2006
Name and mailing address of the international preliminary examining authority: European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Authorized Officer Jonsson, P.O. Telephone No. +49 30 25901-557

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IB2005/000564

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-10	as originally filed

Claims, Numbers

1-12	received on 06.10.2005 with letter of 04.10.2005

Drawings, Sheets

1/2, 2/2	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 10-12

because:

☒ the said international application, or the said claims Nos. 10-12 relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 10-12

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form	☐	has not been furnished
	☐	does not comply with the standard
the computer readable form	☐	has not been furnished
	☐	does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/IB2005/000564

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-9
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-9
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-9
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claims 10-12 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT Rule 39.1(iv) PCT. These claims relates to a method for treatment of the human or animal body by therapy, see also page 5, lines 22-26 of the description. Consequently, no opinion will be formulated with respect to the novelty, inventive step or industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2 Reference is made to the following document:
D1: US-B1-6 208 881;
D2: US 2002/107512 A1;
D3: US-B1-6 579 288;
D4: WO 97/25917 A.

3. NOVELTY AND INVENTIVE STEP, ART. 33(1) - 33(3) PCT:

3.1 The document D1 is regarded as being the closest prior art to the subject-matter of claim 1 and discloses (see col. 3/l.30-35; col. 4/l. 41-col. 5/l. 6; col. 7/l.63-col 8/l. 30; col. 9/l.1-5 and figures 1-3): a catheter (10) for the radiofrequency ablation of tissue (col. 4/l. 47-48) comprising at least one pair of bipolar electrodes (30,32,34,36,38) adapted to function in bipolar mode (col. 3/l. 30-33), each bipolar electrode comprising supply channels (68) adapted for the perfusion of saline solution around the electrodes (col. 8/l. 4-9), the catheter further comprising at least two end electrodes(30,38) arranged towards opposed ends of the catheter (see fig. 1), on either side of the pair of bipolar electrodes, said end electrodes adapted to function in monopolar mode (col. 3/l. 33-35; col. 9/l. 1-5).

Note: As can be seen from figure 7 of D1, *each* individual electrode, also the end electrodes, is foreseen as having an individual feeding cable (18) and thus adapted to function in monopolar and/or bipolar mode as the case may be, see col. 3, lines 30-35; col. 9, lines 1-5. The application of bipolar and/or monopolar mode is a matter more related to the *use* of the catheter and hence not limiting on the device itself.

3.2 The subject-matter of claim 1 therefore differs from this known catheter in that it claims a catheter with a pointed tip for piercing insertion into the tissue.

3.3 The subject-matter of claim 1 is therefore novel (Article 33(2) PCT).

3.4 The problem to be solved by the present invention may therefore be regarded as how to adopt a flexible catheter according to D1, suitable for ablating tissue in the treatment of cardiac arrhythmias, so as to be suitable for ablating tissue in situations where penetration of tissue is necessary.

3.5 The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reason:

In use, a catheter according to D1 is inserted into the ablation area (see D1, col. 1, lines 28 - 38) by a physician steering a catheter having sensing/ablation electrodes on the distal end thereof through the patient's vascular system and into a predetermined chamber of the heart where the treatment is to be carried out.

Although it is known in the art to have pointed electrodes for ablation, see for instance D2, figures 14,15 and par. 81, 82, it is clear that the skilled person would not be hinted towards adopting a pointed tip on a catheter according to D1, since the rounded tip in D1 is made in order prevent penetration during navigation to the ablation site via highly sensitive areas.

Neither of the other documents D3, D4 discloses or even hints towards the use of a pointed tip according to claim 1 and it is thus considered that claim 1 meet the requirements of the PCT with respect to novelty and inventive step.

3.6 Claims 2-6 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step. Claims 7-9 are to an apparatus comprising a catheter according to claims 1-6 and hence also meet the requirements of the PCT with respect to novelty and inventive step.

4. INDUSTRIAL APPLICABILITY, ART. 33(1) AND 33(4) PCT:
The industrial applicability (Art. 33(4) PCT) is clearly given for the subject-matter of all the catheter claims. However, it is noted that no unified criteria exists as regards industrial applicability of methods of treatment of the human or animal body by therapy (see item III above). If the method claims are maintained, this issue will therefore be the subject of further examination in a later regional / national phase.

5. In conclusion claims 1-9 of the Application fulfils the requirements of Art. 33(1) - 33(4) PCT.

Re Item VII

Certain defects in the international application

6. In relation with Article 7(2)(i) PCT it is noted that the figure 1a referred to on page 6 of the description is missing.

Claims

1. Catheter for the radiofrequency ablation of tissue, (with a pointed tip for piercing insertion into the tissue,) comprising at least one pair of bipolar electrodes adapted to function in bipolar mode, each bipolar electrode comprising supply channels adapted for the perfusion of saline solution around the electrodes, the catheter further comprising at least two end electrodes arranged towards opposed ends of the catheter, on either side of the pair of bipolar electrodes, said end electrodes adapted to function in monopolar mode.

2. ~~Device~~ Catheter according to claim 1 ~~2 or 3~~ wherein each bipolar electrode comprises at least two saline solutions supply channels (14a, 15a; 14b, 15b).

3. Catheter according to claim 1 or 2, wherein the liquid supply channels with outlets (15a, 15b) arranged proximate the front and rear ends of the catheter are supplied with the saline solution independently of liquid supply outlets (14a, 14b) arranged proximate the center of the catheter.

4. ~~Device~~ Catheter according to claim 1, ~~or~~ 2 or 3 further comprising a central electrode (8) arranged between the bipolar electrodes (4, 5), the central electrode adapted to function in monopolar mode.

5. ~~Device~~ Catheter according to any one of the preceding claims, further comprising one or more thermocouples (16), said thermocouples being retractably mounted in the catheter and actionable so as to be inserted into tissue surrounding the catheter.

6. Catheter according to any one of the preceding claims, wherein the liquid supply channel outlets are arranged at a distance (B) from the respective central and end monopolar electrodes, that is sufficient to avoid being in a region of coagulated tissue formed around said monopolar electrodes.

7. Apparatus for radiofrequency ablation of tissue comprising a catheter according to any one of the preceding claims and at least two independently controlled pumps for supplying saline solution to separate supply channels of each bipolar electrode.

8. Apparatus according to the preceding claim, further comprising a temperature acquisition unit connected to thermocouples of the catheter.

9. Apparatus according to either one of the two preceding claims, further comprising an RF generator, whereby the independently controlled pumps, RF generator, and temperature acquisition unit are connected to a computing unit, such as a PC, for monitoring and controlling operations.

10. Method of radiofrequency ablation of tissue, comprising the steps of :

- providing a catheter having at least one pair of bipolar electrodes with saline solution supply channels, and at least two monopolar electrodes arranged towards opposed ends of the catheter on either side of the pair of bipolar electrodes;

- inserting the catheter into a central region of the volume of tissue to be ablated;

- supplying electrical power to the monopolar electrodes to coagulate tissue therearound and seal the puncture performed by the catheter;

- perfusing saline solution into the tissue surrounding the bipolar electrodes and supplying electrical RF energy to the bipolar electrodes for thermal ablation.

11. Method according to the preceding claim, wherein the step of perfusing saline solution comprises supplying saline solution via supply channels (14a,

14b) arranged proximate the center of the catheter at a concentration lower than saline solution supplied to outlets (15a, 15b) arranged proximate opposed ends of the catheter.

12. Method according to either one of the two preceding claims, wherein prior to or during the step of operation of the bipolar electrodes, retractable thermocouples (16) mounted in the catheter are inserted at a certain depth into the surrounding tissue.